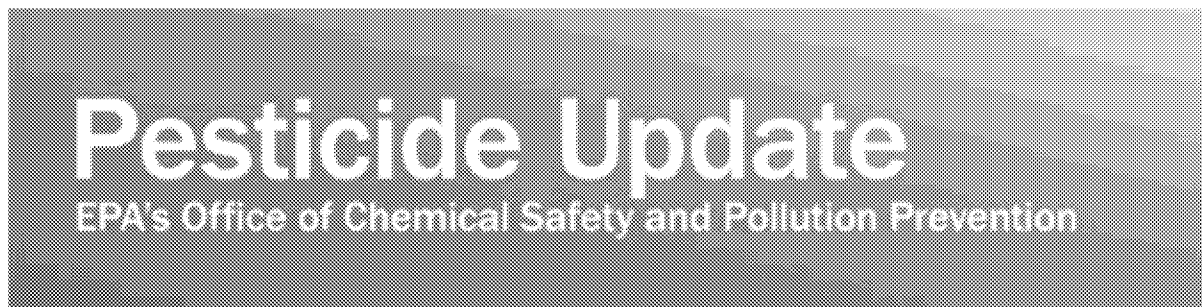


From: Amy Sullivan [aapco.sfireg@gmail.com]
Sent: 3/7/2022 9:33:06 PM
Subject: Fwd: Following Review of Available Data and Public Comments, EPA Expands and Extends Testing of Genetically Engineered Mosquitoes to Reduce Mosquito Populations

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From: U.S. EPA Office of Chemical Safety and Pollution Prevention <oppt.epa@public.govdelivery.com>
Date: Mon, Mar 7, 2022 at 4:32 PM
Subject: Following Review of Available Data and Public Comments, EPA Expands and Extends Testing of Genetically Engineered Mosquitoes to Reduce Mosquito Populations
To: <aapco.sfireg@gmail.com>



Following Review of Available Data and Public Comments, EPA Expands and Extends Testing of Genetically Engineered Mosquitoes to Reduce Mosquito Populations

EPA has approved an experimental use permit (EUP) amendment for Oxitec Ltd. that expands and extends the testing of genetically engineered *Aedes aegypti* (OX5034) mosquitoes to reduce mosquito populations. Prior to approval, EPA conducted extensive evaluation of the best-available science and feedback received during the public comment period.

The original EUP, granted in May 2020, allowed Oxitec to field test the use of OX5034 mosquitoes in Florida and Texas through April 2022. The EUP amendment:

- Extends the EUP until April 30, 2024, on 5,360 acres of Monroe County, Florida. This extension will generate additional data to evaluate the effectiveness of OX5034 mosquitoes at reducing mosquito populations. Oxitec has not reported any adverse effects from the field tests that have been conducted in Florida since April 2021.
- Expands the EUP to four counties in California for the first time, consisting of 29,400 acres in Stanislaus, Fresno, Tulare, and San Bernardino counties. Oxitec may conduct testing in these areas until April 30, 2024, to generate efficacy data in different climactic zones.

- Removes Harris County, Texas, from the approved testing locations because no field tests were conducted in the state during the initial EUP.

Aedes aegypti mosquitoes, which are among the most common invasive mosquito species in the United States, can transmit diseases such as dengue, Zika, and chikungunya to humans; therefore, mosquito control is important for protecting human health. Additionally, the use of species-specific modified mosquitoes could reduce the use of pesticides for mosquito control. This may be especially beneficial for densely populated communities with environmental justice concerns. These communities could be at higher risk for exposure to mosquitoes, virus transmission, and exposure to pesticides from mosquito control.

Like all pesticides, Oxitec's genetically engineered mosquitoes are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Data submitted by Oxitec demonstrate that OX5034 mosquitoes meet FIFRA standards of not causing unreasonable adverse effects to humans or the environment.

The Florida Department of Agriculture and Consumer Services and the California Department of Pesticide Regulation must approve testing in their states before additional testing can take place. Following state approval, Oxitec may release adult male OX5034 mosquitoes, which do not bite people, in the approved release areas. The male mosquitoes have a protein (the tTAV-OX5034 protein) that prevents female offspring from surviving when male OX5034 mosquitoes mate with wild female mosquitoes. The absence of female mosquitos in the release area results in mosquito population decline.

As part of EPA's risk assessment for the EUP amendment, including the extension in Florida and the expansion to California, the Agency examined whether the release or consumption of OX5034 male mosquitoes would harm endangered species or any other organisms such as birds, bats, or fish and determined that no discernible effects are anticipated to these organisms. Additionally, animals are not expected to be harmed from the potential reduction in the local *Aedes aegypti* population because predators that eat mosquitoes generally have a diverse diet and none are known to use *Aedes aegypti* mosquitoes as a sole or critical food source.

To ensure that no OX5034 female mosquito offspring survive, EPA has taken the precaution of restricting release of OX5034 mosquitos within 500 meters of potential sources of tetracyclines, as there is a remote chance that environmental sources of tetracycline could have enough tetracycline present to act as a counter agent to the OX5034 female mosquito-lethal trait. Releases must not occur within 500 meters from the outer perimeter of 1) wastewater treatment facilities; 2) commercial citrus, apple, pear, nectarine, and peach crops; and 3) commercial cattle, poultry, and pig livestock facilities. The 500-meter distance creates a conservative buffer zone between OX5034 release points and potential environmental tetracycline sources.

Additionally, EPA mandates that Oxitec monitor and sample the mosquito population every week to ensure no OX5034 female mosquito offspring survive. When potential environmental tetracycline sources exist within 1,000 meters of mosquito release sites, Oxitec must monitor for OX5034 female mosquitoes within 100 meters of those potential environmental tetracycline sources. No genetically modified female OX5034 mosquitoes have been detected during Oxitec's field testing so far, and no detections are expected based on EPA's risk assessment. If an unforeseen detection occurs, Oxitec must cease releases of all OX5034 mosquitoes and apply adulticide and larvicide pesticides to the treated area where the surviving females were detected and continue to monitor for the presence of OX5034 female mosquitoes. EPA continues to maintain the right to cancel the EUP at any point during the 24-month period.

To view the EUP amendment, the updated risk assessment, and other supporting materials, visit docket [EPA-HQ-OPP-2019-0274](#). To learn more about Oxitec's initial EUP, view EPA's [webinar recording](#), which is available with English or Spanish subtitles.

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Amy Sullivan
Executive Secretary
AAPCO-SFIREG
406-431-3176
aapco.org
<https://twitter.com/aapcoexecsec>